K050931

Section 6

JUN 15 2005

510(k) Summary

6 Fr DL PowerPICC™ Catheter

510(k) Summary of Safety and Effectiveness Information
21CFR 807.92

6.1 Submitter Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Subsidiary of C.R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 4903
Fax Number:	(801) 595-5425
Contact Person:	Peggy Keiffer
Date of Preparation:	April 13, 2005

6.2 Device Name

Device Name:	6 Fr DL PowerPICC™ Catheter
Trade Name:	6 Fr DL PowerPICC™ Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Panel:	General Hospital
Classification Name:	80LJS – Long Term Intravascular Catheter 21 CFR 880.5970, Class II Peripherally Inserted Central Catheter (PICC)

6.3 Predicate Device Name(s)

Device Name:	5 Fr SL PowerPICC™ Catheter
Trade Name:	5 Fr SL PowerPICC™ Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS)
Premarket Notification:	K033389, concurrence date – March 19, 2004

Device Name:	Poly Per-Q-Cath PICC Catheter
Trade Name:	Poly Per-Q-Cath PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS)
Premarket Notification:	K034019, concurrence date – January 21, 2004

6.4 Device Description

- The PowerPICC™ Catheters are open-ended radiopaque polyurethane catheters.
- Catheter size is 6 Fr DL with 50 cm usable length.
- The catheter has a reverse taper design.
- Catheter shaft tubing is marked with depth indicators, with "0" indicated to serve as a reference for the catheter insertion point.
- Catheters are provided sterile in basic radiology PICC configurations.

- Purple colorants were added to the catheter materials to provide the catheter with an appearance that allows the end user to differentiate the **PowerPICC** from other PICC catheters.
- The catheter extension leg, junction and clamp ID tag were printed with markings to identify the catheter as **PowerPICC** and to include information to facilitate proper use of the device.

6.5 Intended Use

The PowerPICC™ Catheters are intended for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling.

The intended use has not changed.

6.6 Indications for Use

The indications for use have not changed from the predicate 5 Fr SL PowerPICC™ catheter (K033389).

The PowerPICC™ catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the PowerPICC catheter may not exceed 300 psi.

6.7 Summary of Technological Characteristics in Relation to the Predicate Device

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all regards. The 6 Fr DL PowerPICC™ catheter has some minor differences from the predicate 5 Fr SL PowerPICC™ catheter. However, the basic fundamental scientific technology of the catheter has not changed.

Could the new characteristics affect safety or effectiveness?

Yes. The new characteristics could affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new types of issues of safety and effectiveness.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The following FDA guidance documents and international standards were used to evaluate the device's performance:

- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995*
- *ISO 10555-1:1997, Sterile, Single-Use Intravascular Catheters, General requirements*
- *ISO 10555-1:1997, Sterile, Single-Use Intravascular Catheters, General requirements, Amendment 1*
- *ISO 10555-3:1997, Sterile, Single-Use Intravascular Catheters, Central venous catheters*
- *AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*

No new design validation was required. The design validation for the predicate device covered all issues pertaining to the subject device

Biocompatibility requirements of ISO 10993 *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing* and the FDA Modified ISO 10993 Test Profile for externally communicating, blood contacting, long-term devices were met. All materials used in the manufacture of the subject device were previously cleared for similar applications by Bard Access Systems.

Are performance data available to assess effects of new characteristics?

Yes. Verification and validation testing was performed according to protocols based on the above referenced guidance document recommendations and standards, as well as in accordance with in-house protocols.

Do performance data demonstrate equivalence?

Yes. Performance data gathered in design verification testing demonstrated that the 6 Fr DL PowerPICC™ catheter is substantially equivalent to the predicate 5 Fr SL PowerPICC™ catheter, and the risks associated with use of the new device were found acceptable when evaluated by FMEA.

6.8 Conclusion

The 6 Fr DL PowerPICC™ catheter meets all the predetermined performance acceptance criteria of the testing performed and, based on FDA's decision tree, is substantially equivalent to the predicate device 5 Fr SL PowerPICC™ catheter, K033389, cleared March, 2004 and the Poly Per-Q-Cath PICC Catheters, cleared under K034019.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2005

Ms. Peggy Keiffer
Senior Regulatory Affairs Manager
Bard Access System, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K050931
Trade/Device Name: 6 Fr DL PowerPICC™ Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 28, 2005
Received: May 17, 2005

Dear Ms. Keiffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

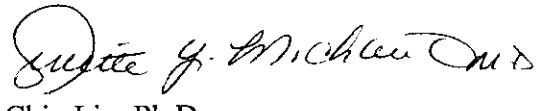
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 050931

Section 1.2

Indications for Use Statement

510(k) Number (if known):

Device Name: 6 Fr DL PowerPICC™ Catheter

Indications For Use:

The **PowerPICC™** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the **PowerPICC** catheter may not exceed 300 psi.

Prescription Use ___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050931